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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/995,860	11/29/2001	Geert Maertens	2551-69	4135

23117 7590 06/02/2005

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EXAMINER	
LI, BAO Q	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 06/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/995,860	MAERTENS ET AL.	
	Examiner	Art Unit	
	Bao Qun Li	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16,17 and 20-43* is/are pending in the application.

4a) Of the above claim(s) *27-35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16,17,20-26 and 36-43* is/are rejected.

7)☒ Claim(s) *36,37,40 and 43* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/355,040.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *02/22/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *sequence letter*.

DETAILED ACTION

RCE

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02/22/2005 has been entered.

Regarding to request of refund the money, applicants argue that including claim 17 in the previous outstanding rejection is a new ground rejection. Therefore, the final rejection made in the previous Office Action is premature. The argument has been fully considered; however, it is not persuasive because the rejection for claim 17 that applicants asked for is based on the request by the applicants for rejoining the claim since there is no extra burden for searching the limitation in the cited reference of the outstanding prior art rejection, and the reference teaches the limitation of claim 17. Moreover, the basis for rejection is based the same reference rather than any new reference or any new opinion inconsistent with that used in the previous office Action. Therefore, the Final rejection made by the previous Office Action is not a premature Final Office action. The money paid for processing the REC is required.

Response to Amendment

This is a response to the amendment filed 02/22/05. Claims, 27, 29, 31, 33-36 have been amended. The status of each claims are summarized as following:

Claims 1-15, 18-19 have been canceled.

Claims 16-17, and 20-43 are pending.

Upon reconsidering the pending claims after the amendment filed by the application on February 22, 2005, claims 16-17, 20-26, 36-43 are considered.

Claims 27-35 are withdrawn from the consideration.

Please note any ground of rejection(s) that has not been repeated is removed. Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Petition under 1.81

1. Applicants filed a petition on restriction requirement after the first office action on July 17, 2004. In that petition, Applicants asked for rejoined Group I-III since there is no burden for searching one or more HCV envelope protein from same or different strains of HCV. The petition along with the amendments filed during the prosecution has been fully considered by the examiner prior to issue the previous office actions and current office action as stated above. Groups I-III related claims 16-17, 20-26, 36-43 have been rejoined and considered by examiner before issuing the previous Office Actions and current Office Action. The petition request has been submitted to the petition's office in the TC16000, they will mail the decision after the decision is made.

Information Disclosure Statement

2. The information disclosure statement (IDS) filed on 02/22/2005 has been acknowledged and considered. The 1449 form is initialed and returned alone with this office action.

Sequence requirements

3. This application contains sequence disclosures on **page 85** that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, they fail to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

4. Full compliance with the sequence rules by inserting the sequence identification number (SEQ ID NO:) complying with the sequence rule is required in response to this Office Action. A complete response to this office action should include both compliance with the sequence rules and a response to the Office Action set forth below. Failure to fully comply with **both** these requirements in the time period set forth in this office action will be held non-responsive.

Specification

5. The objection of E1s has been removed in view of applicants' argument that parental case has a definition of E1s.

Double Patenting

6. Claims 15, 16, 17, 18, 21-26, 36-39, 40 and 43 are still rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13, 16 and 21 of U.S. Patent No. 6, 635,257 B1 and the copending application No. 09/995, 791 on the same ground as stated in the previous Office Action. Because applicants did not address these issues, the rejections are maintained.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 16, 17, 20-26, 36, 37, 38, 39, and 40-43 are still rejected under 35 U.S.C. 102(b) as being anticipated by Maertens et al. (WO 96/04385A2) on the same ground as stated in the previous Office Action.

9. Applicants traverse and submit that Patent Office has consistently stated that the disclosure of WO96/043850A2 failed to provide an enabling disclosure for a vaccine of the sort being presently claimed during prosecution of application serial Number 08/928,757. Therefore, the patent office cannot rightfully now hold that the same disclosure can be an anticipation of a vaccine claim.

10. Applicants' argument has been fully considered. However, it is not persuasive to overcome the rejection. The issue of this 102 rejection application is whether or not the disclosure of WO96/043850A2 is available as prior art, and this issue turns upon whether or not the invention as claimed is enabled by the vaccine claims in other US application 08/928,757.

11. Applicants are reminded that each application is treated on its own merits. The anticipatory issue is dependent on whether the prior art has a disclosure of claimed product that has the same structure or as the method of making the same product regardless of the disclosure of enabled or not-enabled utility. To quote Robert L. Harmon in the reference book Patents and the Federal Circuit, Fifth Edition, (BNA Books, Washington DC, 2001, page 85): "If

compositions are known, for any use or no use, they are not patentable as compositions, by force of §102...It is beyond argument that no utility need be disclosed for a reference to be anticipatory of a claim to an old compound." WO96/043850A2 teaches how to make the composition comprising the same HCV envelope protein product that applicants are claiming, and WO96/04850A2 conveys possession of the composition by disclosing its full structure and a method of making the same. Therefore, the disclosure in WO96/04850A2 is sufficient for anticipation, regardless of what WO96/04850A2 may teach or fail to teach about how to use the composition. Therefore, Applicant's arguments are unconvincing, and the rejection is maintained.

12. Regarding to the recitation of "therapeutic vaccine", the recitation is only considered as a preamble language that serves to describe the intended use, because is does not change the structural of claimed product. If the product disclosed in the prior art possesses the same structural characteristic, it is capable of performing the same intended use of the rejected claim. To this context, the cited prior art meets the claim. Especially, the definition of the therapeutic vaccine is defined by the specification as a composition producing a therapeutic effect rather than prevention. The claimed invention is therefore, anticipated by the cited references. The rejections are maintained.

13. The prior art rejections under 35 U.S.C. 102(b) by Choo et al. (P.N.A.S. USA, 1994, Vol. 91, pp. 1294-1298), Houghton et al. (A) (Prospects for prophylactic and therapeutic hepatitis C virus vaccines. Princess Takamatsa Symp. 1995, Vol. 25, pp. 237-243) and Houghton et al. (Proceeding of IX Triennial International Symposium on viral hepatitis and liver disease, Rizetto Purcell, gerin, Verme, eds. Edizioni Minerva Medica, Italy, 1997, pp. 656-657) are withdrawn in view of the amendment of claim 16 in that the claim recites that the composition consists of E1 glycoprotein only. In contrast, all prior art teach that the immunogenic compositions comprise E1 and E2.

New Ground Rejections:

Specification

14. The disclosure is objected to because of the following informalities: In line 9 of page 75, the cited patent number of WO 99/97285 should be corrected as WO99/67285. Appropriate correction is required.

15. The specification is objected as to failing to provide a proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: In the instant case, the antecedent bases for "a specific oligmeric envelope E1 protein" and "a part thereof" cited in claims 16 and 17 cannot be found in the specification.

Claim Rejections - 35 USC § 112

16. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

17. Claims 16-17, 21-26,36-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

18. Claims 16 and 17 are vague because it is unclear what the recited specific oligmeric envelope E1 protein is referred to. The claims are interpreted in light of the specification; however, the specification does not teach what the specific oligmeric envelope protein E1 is referred to. Therefore, the claims are considered indefinite. This affects the dependent claims 20-26, 36-43.

Double Patenting Objection

19. Claim 36 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 37. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

20. Claim 40 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 43. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

21. Applicant is advised that should claim 36 be found allowable, claim 37 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

22. Applicant is advised that should claim 40 be found allowable, claim 43 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Double Patenting Rejection

23. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

24. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

25. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

26. An obviousness-type double-patenting rejection is appropriate where the conflict claims are not identical but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim(s) is either anticipated by or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 14U F.3d 1428, 46 USPQZd 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQZd 2010 (Fed. either anticipated by, 1993); In re Longi, F.2d 887, 225 US/Q 645 (Fed. Cir. 1985).

27. Claims 16, 36, 37, 40 and 43 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 65, 68, 69, 72, 75, 76 of copending Application No. 08/928,757. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scopes of conflict claims are overlapping.

28. In particular, both sets of claims are directed to an immunogenic composition and method of using the composition, wherein the composition comprises at least one HCV single or specific HCV envelope protein and at least other components including a pharmaceutical accepted carrier, adjuvant or vehicle. The scope of current application is limited to the oligomeric HCV E1 envelope protein or part thereof, whereas the scope of conflict claims in application No. 08/928,757 is broadly directed to a composition comprising at least one purified recombinant HCV envelope protein selected from E1 and E2. Considering the E1 envelope proteins cited in both applications are all produced by the same recombinant procedure with same construct and same host cell as disclosed of the specification, they are considered as a same HCV envelope protein comprised in an immunogenic composition as deferent obvious embodiment. Nevertheless, the disclosure of the conflict claims still contains the scope of the composition comprising the HCV E1 envelope protein and other same components as claim 16 cited, the scopes of conflict claims and the rejected claims are overlapping. Therefore, the disclosure of conflict claims anticipates the claims 16, 36, 37 and 40 of current application.

29. Regarding to this rejection, applicants' attention is directed to the case law of *In re Sussman*, 141 F. 2d 267, 60 U.S.P.Q. 538 (CCPA 1944), which cites "since the steps are the same, the results must inherently be the same unless they are due to conditions not recited in the claims." In the instant case, Applicant(s) is (are) claiming an invention employing the **same process steps** but the product(s) is(are) **alleged to be different**. If the claimed products are structurally different, Applicant is required to recite the missing steps to form the alleged different product(s) in view of the above cited decision.

30. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

31. Claims 36, 37, 40 and 43 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 50, 53, 54, 63-65, 67-70 of copending Application No. 10, 321, 798. Although the conflicting claims are not identical, they are not patentably distinct from each other because:

32. Both of sets of claims are directed to a method of using an immunogenic composition for treating the disease caused by HCV infection, wherein the composition comprises at least one HCV envelope E1 protein or part thereof, pharmaceutical accepted carrier, adjuvant or vehicle. The scope of current application is more generally directed to a method for treating any or all HIV infected diseases in mammal, especially for human with the oligomeric HCV E1 envelope protein or part thereof, whereas the scope of conflict claims in application 10,321,798 is directed to use the composition comprising HCV envelope E1 polypeptide ranging from amino acid residues 192-326 for treating some particular symptom caused by HCV infected liver disease. Therefore, the method of the conflict claims in the application No. 1, 132, 798 is a species of the general claimed method in the current application, and it anticipates the claims 36, 37, 40 and 43.

33. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

34. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

35. Claims 16-17, 20-27, 36-43 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while enabling for producing an immune response by administering a therapeutic composition into chimpanzees, wherein the composition comprises HCV envelope protein E1s amino acid residues 192-326 that is produced as a properly core-glycosylated glycoprotein by eukaryotic vero cell, does not reasonably provide enablement for having a therapeutic HCV vaccine composition made by any part of HCV E1 envelope protein , which is able to treat any or all homologous and heterologous HCV infections. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

36. The rejection of these claims under 35 U.S.C. 112 has been withdrawn in the previous Office action. However, after reconsidering the broad scope of claimed invention, it read as a therapeutic vaccine composition comprising any or part of HCV E1 for treating both homologous and heterotopous HCV infection, the rejection is reestablished.

37. The test of the enablement is whether one skilled in the art could make and use the claimed invention from the disclosures in the application coupled with information known in the art without undue experimentation (See United States v. Theketronic Inc., 8USPQ2d 1217 (fed Cir. 1988). Whether undue experimentation is required is not based upon a single factor but rather a conclusion reached by weighting many factors. Theses factors were outlined in Ex parte Forman, 230 USPQ 546 (Bd. Pat. App. & Inter. 1986) and In re Wands, 8USPQ2d 1400 (Fed. Cir. 1988). The following paragraphs are the analysis based on those factors.

38. Nature of invention and scope of claims: The present invention is directed to a recombinant HCV envelope protein E1 consisting of amino acid residues 192-324 carried by a recombinant vaccinia virus vector is produced as a properly glycosylated glycoprotein in a eukaryotic host cell, and a composition made by such glycoprotein with other pharmaceutical accepted carrier and adjuvant. The invention is also directed to use such composition for

inducing an immune response in HCV chronically infected patients and reduce the clinical symptom. However, the broad scope of claims is directed to a therapeutic vaccine composition comprising at least one singular or specifically oligomeric HCV envelope protein E1 or a part of HCV E1. Since the specification does not have the definition of " part thereof", a reasonable interpretation of the broadest scope of "part of HCV envelope can be a single amino acid of HCV E1 protein.

39. State of art and Unpredictable field: The state of art teaches that HCV is particular difficulty to study and control. Even applicants has published their results of using the recombinant HCV E1 as a composition to treat some HCV chronically infected patients, the state of art commented that the results are inconclusive as evidenced by Ghany et al. (Hepatology 2003, Vol. 38, No. 5, pp. 1092-1093). The unpredictility of using HCV envelope protein or even any part of the HCV E1 envelope protein as a therapeutic vaccine is because:

a. The HCV is a virus with a intrinsic hypermutability, 1.e. the varies and mutated greatly and frequently within the strain and even within the individual patients over time as evidenced by Wang et al. (J. Immunol. 1999, Vol. 162, pp. 4177-4183). Therefore, HCV contains many quansispecies. The immune escape occurs due to this characteristic. For example, that the recombinant HCV E1 or E2 is only able to prevent experimental infection caused by the homologous infection but not heterologous infection (See Ghany et al. on page 1092, 2nd column).

b. The immune response induced by HCV antigen is relative lower as compared with many other antiviral responses as taught by Lechner et al. (The Royl Society 2000, Vol. 355, pp. 1085-1092, see pages 1090-1091) and Bukh et al. (Intervirology 2001, Vol. 44, pp. 132-142, see pages 139-142). Therefore, the immune respond induced by the properly core-glycosylated HCV E1 of amino acid residues of 192-324 may not be reproduced by any part of HCV E1 envelope protein because induction of a proper immune response requires the integrity of a right antigen with a its proper tertiary structure. Different glycosylation in the 5 or 6 N-glycosylation sites of HCV envelope protein influence the immunogenicity of the HCV envelope protein E1 as evidenced by Fournillier et al. (J. Virol. 2001, Vol. 75 No. 24, pp. 12088-120977, see pages 12091-

12093). This unpredictability is also addressed by the disclosure of applicants' own application (See page 1, lines 19-30).

c. The immune response induce by HCV E1 does not reduce the HCV RNA in the patients and improve their lever functions, which are the essential elements for accessing any therapeutic effect against HCV infection in the clinic. Actually, no patients achieved viral clearance after treatment of HCV E1. Therefore, the expertise in the field concluded that HVC E1 can not recommended as HCV treatment strategy as either initial therapy or maintenance therapy (See entire document of Ghany et al. especially on page 1092 and 1094).

40. Number of working examples and Amount of guidance: Applicants only teach to use HCV E1 polypeptide (aa 192-326) for inducing both humoral and cellular immune responses in a chimpanzees. The specification does not provide sufficient evidence to support that any part of HCV is able to be used as an effective therapeutic composition and control the ongoing HCV infection in a patient who has already suffered from either homologous or a heterologous HCV infection. Applicants do not teach to use more than one HCV envelope protein E1 derived from different strains to constitute a composition for controlling any homologous and heterologous HCV infection in a HCV infected patient. Applicants present no guidance on how the skilled artisan would practice successfully using any or all part of HCV E1 protein to produce a therapeutic vaccine to treat HCV infection.

41. Level of the skill in the art: The invention involves one of the most complex and unpredictable fields of treating chronic HCV infection. The level of skill in the art requires considerable high. So far, there is still a significant hurdles remain to be overcome.

42. Given the above analysis of the factors, which the courts have determined, are critical in asserting whether a claimed invention is enabled, it must be considered that the skilled artisan would have to conduct undue and excessive experimentation in order to practice the claimed invention.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 7:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Baoqun Li

Bao Qun Li

May 23, 2005

Notice to Comply	Application No.	Applicant(s)	
	Examiner	Art Unit	

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☒ 7. Other: See office action for detial

Applicant Must Provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216
For CRF Submission Help, call (703) 308-4212
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